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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/185,607	11/04/1998	SHUI-ON LEUNG	018733/0875	5589

7590 06/05/2002
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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/05/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/185,607

Applicant(s)

LEUNG ET AL

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-19 and 21-55 is/are pending in the application.
- 4a) Of the above claim(s) 15,28 and 30-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-14,16-19,21-27,29 and 38-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 5/21/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/185,607 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 1, 4-19, 21-55 are pending.

Claims 39, 42, 45, and 51 have been amended in the response filed 12/21/01 which WAS entered as stated in the Advisory Action mailed 1/10/02.
3. Claims 15, 28, and 30-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made **without** traverse in Paper No. 12.
4. Claims 1-2, 4-14, 16-27, 29, and 38-55 are under examination.
5. The text of those sections of Title 35, U.S.C. Code not included in this Office Action can be found in a prior Office Action.
6. **NOTE:** The amendment filed 12/21/01 has been entered as stated in the Advisory Action mailed 1/10/02 and all arguments have been considered and addressed in the Advisory Action mailed 1/10/02. The response filed 5/21/02 which requested a CPA filing also requested that the amendment filed on 12/21/01 be entered. As stated the amendment was entered and considered in the Advisory Action mailed 1/10/02.

The filing of the CPA on 5/21/02 did not provide any additional arguments or amendments to the claims.

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Rejections Withdrawn

7. The rejection of claims 1, 4-14, 16-18 38-39, 41-42, 44-45, 47-48, 50-51 and 55 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn as stated in the Advisory Action mailed 1/10/02.

8. The rejection of claims 39-40, 42-43, 45-46, 48-49, 51-52 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn as stated in the Advisory Action mailed 1/10/02..

Response to Arguments

9. The rejection of claims 1-2, 4-14, 16-19, 21-27, 29, 38, 41, 44, 47, 50, 53-55 under 35 U.S.C. 112, first paragraph, is maintained.

The response filed 12/21/01 has been carefully considered but is deemed not to be persuasive. The response states "The fact that every site identified by computer modeling as a potential glycosylation site is not, in practice, glycosylated does not, however, lead to a conclusion that the present claims are not enabled". (see page 5 of response). In response to this argument, while it may be true that one can screen for glycosylated sites, it is not clear from the specification what of the many saccharide precursors or "ketone derivatives" would work in the claimed method. The specification does not enable any other "ketone derivatives of saccharides and saccharide precursors" other than N-levulinoyl mannosamine and N-levulinoyl fructose and it would

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require undue experimentation to determine which ketone derivatives (or how they are “derived”) of saccharides and saccharide precursors other than N-levulinoyl mannosamine and N-levulinoyl fructose would work in the claimed method and result in a glycosylated antibody or antigen binding fragment

10. The rejection of claims 39-40, 42-43, 45-46, 48-49, and 51-52 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is maintained.

The response filed 12/21/01 has been carefully considered but is deemed not to be persuasive. The response was addressed in the Advisory action mailed 1/10/02 and is restated. The response filed 12/21/-1 has been carefully considered but is deemed not to be persuasive. The response states “the sequence of the hLL2 antibody is known” and “sequences of hLL2HCN1 and hLL2HCN5 are described in U.S. 6,254,868”. In response to this argument, a deposit is required because the claims are directed to an entire antibody and US Patent 5,789,554 recites the VH and VL and no other sequences such as the hinge, CH1, CH2, or CH3 and Patent 6,254,868 also does not have this information. Also claims 39, 42, 45, 48, and 51 which are newly amended

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are also rejected under 112 1st for deposit of the recited antibodies hLL2CN1, hLL2HCN5, and hLL2Vk-N. Therefore the 112 1st is maintained for deposit.

11. The rejection of claims 19, 21-26 and 53-55 under 35 U.S.C. 103(a) as being unpatentable over Shih et al (U. S. Patent 5,057,313, issued 10/15/91) and further in view of Leung et al (int. J. Cancer 60:534-538, 1995, IDS #5) and Qu et al (Glycobiology 7:803-809, 9/97, IDS #5) is maintained.

The response filed 12/21/01 has been carefully considered but is deemed not to be persuasive. The response was addressed in the Advisory action mailed 1/10/02 and is restated. The response seems to be addressing the art that Shih does not disclose a glycosylated antibody having a reactive ketone group on the glycosylated site that is not introduced by hash oxidation and McKearn does not disclose such a glycosylated antibody prepared by the method of claim 1 (see pages 6-7 of response). In response to these arguments, the rejected claims are to products that have a reactive ketone group on the glycosylated antibody and Shih teach this product. It is immaterial how product is made when the claims are directed to a product.

Claim 55 is directed to an antibody prepared by the method of claim 1. Applicant is reminded that when the claim is directed to a product, the preamble is generally nonlimiting if the body of the claim is directed to an old composition and the preamble merely recites a property inherent in the old composition. [*Kropa v. Robie*, 88 USPQ 478, 480 - 81 (CCPA 1951); see also MPEP 2111.02.

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Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusions

12. No Claims are allowed.

13. This is a CPA of applicant's earlier Application No. 09/185,607. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879


SHEELA HUFF
PRIMARY EXAMINER